K132242

510(K) Summary

DEC 6 2013

Submitter
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Date prepared: 7/15/2013

Indications for Use

The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework, this system is intended for delayed loading.

The implants with diameters larger than 5.0mm are intended to be surgically placed in the maxillary or mandibular molar areas for the purposed of providing prosthetic support for dental restorations (Crown, bridge, and overdentures) in partially or fully edentulous individuals. These implants are intended to be used where smaller implants have failed.

General Description

The INNO SLA Submerged Implant System is a dental implant made of titanium(Grade 4) metal intended to be surgically placed in the bone of the upper and / or lower jaw arches. This system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The differences between the subject device and the predicate device are shape and surface treatment. The INNO SLA Submerged Implant System has one-stage and two-stage surgery.The surface treatment method of the subject device is S.L.A(Sand-blasted Large grit Acid-etched).

The fixture diameters are 3.7, 4.2, 4.6, 5.1, and 6.0mm and the implant lengths are 7.0, 7.5, 8, 9.5, 10, 11.5, 12, and 14mm in this system. The available lengths for each diameter of the fixtures are the following:

- Ø3.7mm with lengths of 8mm, 10mm, 12mm, and 14mm
- Ø4.2mm with lengths of 8mm, 10mm, 12mm, and 14mm
- Ø4.6mm with lengths of 8mm, 10mm, 12mm, and 14mm
- Ø5.1mm with lengths of 7mm, 8mm, 10mm, 12mm, and 14mm
- Ø6.0mm with lengths of 7mm, 7.5mm, 9.5mm, and 11.5mm

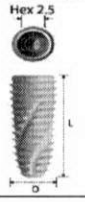
The abutments are made of titanium alloy and plastic and it is intended for use to made temporary prosthesis. It consists of Abutment and Coping Screw. The Abutment diameters are 3.7 ~ 6.5mm, and

lengths 7.9 ~ 17.7mm.

Predicate Devices & Comparison

The subject device is substantially equivalent to the following predicate device:

- Cowell Implant System by Cowellmedi Co., Ltd. (K100850)
- Implantium II by Dentium Co., Ltd. (K060501)

	Subject device	Predicate device	Predicate Device
Device name	INNO SLA Submerged Implant System	Cowell Implant System	Implantium II
510(k) number	N/A	K100850	K060501
Manufacturer	Cowellmedi Co., Ltd.	Cowellmedi Co., Ltd	Dentium Co., Ltd.
Intended use	Identical to predicate	The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework, this is intended for delayed loading. The implants with diameters larger than 5.0mm are intended to be surgically placed in the maxillary or mandibular molar areas for the purposed of providing prosthetic support for dental restorations (Crown, bridge, and overdentures) in partially or fully edentulous individuals. These implants are intended to be used where smaller implants have failed.	Implantium II is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetics devices, such as artificial teeth, and to restore the patient's chewing function.
Material	CP Titanium, Gr.4 ASTM F67	CP Titanium, Gr.4 ASTM F67	CP Titanium, Gr.4 ASTM F67
Design	Submerged	Submerged	Submerged
Fixture Design			

Implant diameter	3.7, 4.2, 4.6, 5.1, 6.0mm	3.6, 3.7, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5mm	3.6 – 7.0 mm
Implant length	7, 7.5, 8, 9.5, 10, 11.5, 12, 14mm	8, 9, 10, 11, 12, 14, 16, 18mm	7 - 14 mm
Components	Various abutments and components	Various abutments and components	Various abutments and components
Surface treatment	SLA	RBM	SLA
Gamma sterilized	Yes	Yes	Yes
Product Code	DZE	DZE	DZE

Comparison Analysis

The INNO SLA Submerged Implant System has a substantially equivalent intended use as the identified predicate. The INNO SLA Submerged Implant System is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments, and they are all constructed of titanium.

INNO SLA Submerged Implant System is substantially equivalent in materials, indications and intended use, packaging, labeling, and performance to the predicate device currently marketed in the U.S.

Only the difference between the subject device and the predicate is the surface treatment method and the Fixture's external design.

Any differences in technology characteristics are accompanied by information that demonstrated the device is safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate

Non-Clinical Data

No additional testing was performed for the subject device.

Conclusion

The INNO SLA Submerged Implant System, subject device of this submission, constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. The risks of using the device as recommended pose no greater risks than other implant systems. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, INNO SLA Submerged Implant System and its predicate devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Cowellmedi Company, Limited
C/O Ms. April Lee
Consultant
Kodent, Incorporated
325 North Puente Street, Unit B
Brea, CA 92821

Re: K132242
Trade/Device Name: INNO SLA Submerged Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 30, 2013
Received: November 1, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K132242

Device Name: INNO SLA Submerged Implant System

The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework, this system is intended for delayed loading.

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Prescription Use ____X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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Susan Runner DDS, MA
Mary S. Runner -S
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